

Assembly Bill No. 549

Passed the Assembly August 26, 2010

Chief Clerk of the Assembly

Passed the Senate August 25, 2010

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2010, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 1209.1 and 1264 of, and to add Section 1264.5 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 549, Furutani. Licensure: clinical laboratory personnel.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Public Health. Existing law requires the department to issue a clinical chemist, clinical microbiologist, clinical toxicologist, clinical molecular biologist, or clinical cytogeneticist license to each person who has applied for the license on a specified form, who also holds a master of science or doctoral degree in the specialty for which the applicant is seeking a license, and who has met other requirements, including the payment of specified application and license fees. Existing law requires the department to determine by examination, except as specified, whether an applicant is qualified. Existing law requires the graduate education to have included 30 semester hours of coursework in the applicants's specialty.

This bill would require the department to issue a clinical biochemical geneticist license to a person meeting these requirements. For the above-enumerated specialties and subspecialties, this bill would specify that a formal letter or other official written documentation issued by an accredited training program indicating that an applicant completed the program, and from a clinical laboratory confirming the applicant's employment experience, shall constitute sufficient evidence. The bill would also require an applicant to provide evidence of satisfactory performance on a written examination in the applicant's specialty or subspecialty administered by an appropriate accrediting body recognized by the department.

This bill would require the department to post application forms and instructions for licensure in clinical laboratory practice on its Internet Web site, to notify an applicant whether the application is complete or requires additional documentation to become

complete. The bill would also require the department to issue a temporary license to an applicant meeting specified experience and certification requirements, within 30 days of determining an application is complete. The bill would also make conforming changes.

The bill would require the department to set and charge application fees sufficient to recover the costs of implementing the provisions of the bill.

The people of the State of California do enact as follows:

SECTION 1. Section 1209.1 of the Business and Professions Code is amended to read:

1209.1. (a) As used in this chapter, “histocompatibility laboratory director” means a physician and surgeon licensed to practice medicine pursuant to Chapter 5 (commencing with Section 2000) who is qualified pursuant to Section 1209, a bioanalyst licensed pursuant to Section 1260 who is qualified pursuant to Sections 1203 and 1209, or a person who has earned a doctoral degree in a biological science, who has completed, subsequent to graduation, four years of experience in immunology, two of which have been in histocompatibility testing.

(b) On and after January 1, 2007, in order to be eligible for licensure as a histocompatibility laboratory director, an applicant who is not a duly licensed physician and surgeon or a duly licensed bioanalyst shall provide evidence of satisfactory performance on a written examination in histocompatibility administered by the American Board of Histocompatibility and Immunogenetics, and have demonstrated satisfactory performance on an oral examination administered by the department regarding this chapter and Part 493 (commencing with Section 493.1) of Subchapter G of Chapter IV of Title 42 of the Code of Federal Regulations.

(c) A person licensed under Section 1260.1 as a histocompatibility laboratory director and qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialty of histocompatibility, immunology, or other specialty or subspecialty specified by

regulation adopted by the department. A person licensed as a “histocompatibility laboratory director” may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(d) The department shall, within 30 days of determining that an application is complete, issue a temporary license to any applicant seeking licensure pursuant to this section, when the applicant meets the following requirements:

(1) The applicant has earned a doctoral degree in a biological science and has completed, subsequent to graduation, four years of training and experience in immunology, of which two years shall have been in histocompatibility testing in a laboratory in any state of the United States or in Canada.

(2) The applicant provides evidence of satisfactory performance on a written examination in histocompatibility administered by the American Board of Histocompatibility and Immunogenetics.

(e) An applicant issued a temporary license pursuant to subdivision (d) shall work only under the supervision of an individual licensed pursuant to Section 1209.

(f) A temporary license issued pursuant to subdivision (d) shall remain valid until the applicant has taken the oral examination offered by the department, the department completes evaluating and processing of the applicant’s results and licensure, and the department has issued a permanent license. If the applicant fails to pass the required oral examinations, the department may revoke the temporary license upon notice to the applicant sent by first-class mail.

(g) The department shall set and charge an application fee in an amount sufficient to recover the costs of issuing a temporary license pursuant to subdivision (d).

SEC. 2. Section 1264 of the Business and Professions Code is amended to read:

1264. The department shall issue a clinical chemist, clinical microbiologist, clinical toxicologist, clinical molecular biologist, clinical biochemical geneticist, or clinical cytogeneticist license to each person who has applied for the license on forms provided by the department, who is a lawful holder of a master of science or doctoral degree in the specialty for which the applicant is seeking a license, and who has met such additional reasonable qualifications of training, education, and experience as the

department may establish by regulations. The department shall issue an oral and maxillofacial pathologist license to every applicant for licensure who has applied for the license on forms provided by the department, who is a registered Diplomate of the American Board of Oral and Maxillofacial Pathology, and who meets any additional and reasonable qualifications of training, education, and experience as the department may establish by regulation.

(a) (1) Unless otherwise required by regulation, the graduate education shall have included 30 semester hours of coursework in the applicant's specialty. Applicants possessing only a master of science degree shall have the equivalent of one year of full-time, directed study or training in procedures and principles involved in the development, modification, or evaluation of laboratory methods, including training in complex methods applicable to diagnostic laboratory work. Each applicant must have had one year of training in his or her specialty in a clinical laboratory acceptable to the department and three years of experience in his or her specialty in a clinical laboratory, two years of which must have been at a supervisory level. The education shall have been obtained in one or more established and reputable institutions maintaining standards equivalent, as determined by the department, to those institutions accredited by an agency acceptable to the department. The department shall determine by examination that the applicant is properly qualified. Examinations, training, or experience requirements for specialty licenses shall cover only the specialty concerned.

(2) A formal letter or other official written documentation issued by an accredited training program indicating that the applicant has completed the program, and from a clinical laboratory or laboratories confirming the applicant's employment experience as required by regulation, shall constitute sufficient evidence for the purpose of this subdivision. Each applicant shall also provide evidence of satisfactory performance on a written examination in the applicant's specialty or subspecialty administered by an appropriate accrediting body recognized by the department. In order to constitute sufficient evidence for this purpose, formal letters or other documentation required by this paragraph shall be provided directly by the examining agency or appropriate accrediting body to the department.

(b) The department may issue licenses without the examination required by paragraph (1) of subdivision (a) to applicants who have passed examinations of other states or an appropriate accrediting body whose requirements are equal to or greater than those required by this chapter and regulations established by the department. The evaluation of other state requirements or requirements of appropriate accrediting bodies shall be carried out by the department with the assistance of representatives from the licensed groups. This section shall not apply to persons who have passed an examination by another state or appropriate accrediting body prior to the establishment of requirements that are equal to or exceed those of this chapter or regulations of the department.

(c) The department may issue licenses without examination to applicants who had met standards of education and training, defined by regulations, prior to the date of the adoption of implementing regulations.

(d) The department shall, within 30 days of determining that an application is complete, issue a temporary license to any applicant seeking licensure pursuant to this section, when the applicant meets the following requirements:

(1) The applicant has earned a doctoral degree in a biological science and has completed, subsequent to graduation, four years of training and experience in the area of specialty or subspecialty for which he or she is seeking licensure in any state of the United States or in Canada and the applicant's license remains in good standing.

(2) The applicant has board certification from an appropriate body recognized by the United States Department of Health and Human Services in the area of specialty or subspecialty for which he or she is seeking licensure.

(e) An applicant issued a temporary license pursuant to subdivision (d) shall work only under the supervision of an individual licensed pursuant to Section 1209.

(f) A temporary license issued pursuant to subdivision (d) shall remain valid until the applicant has taken the oral examination offered by the department, the department completes the evaluation and processing of the applicant's results and licensure, and the department has issued a permanent license. If the applicant fails to pass a required examination, the department may revoke the

temporary license upon notice sent to the applicant by first-class mail.

(g) The department shall adopt regulations to conform to this section.

(h) The department shall set and charge an application fee in an amount sufficient to recover the costs of issuing a temporary license pursuant to subdivision (d).

SEC. 3. Section 1264.5 is added to the Business and Professions Code, to read:

1264.5. (a) The department shall maintain an expeditious process for licensing applicants for licensure in clinical laboratory practice. Application forms and instructions for each category of licensure shall be posted on the department's Internet Web site.

(b) After receiving an application for licensure in clinical laboratory practice, including a resubmission of an application, the department shall notify the applicant in writing or by electronic mail that the application is complete and shall be processed by the department or that the application is incomplete. If the application is incomplete, the department shall specify in the notification the transcripts, board certification, verification of training, or other documents required to complete the application for licensure that have not been received by the department.

(c) The department shall set and charge application fees in amounts sufficient to recover the costs of implementing this section.

Approved _____, 2010

Governor